

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001	Appln. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

## U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
/J.P./	6,358,944	3/19/02	Lederman et al.	514	220	
/J.P./	6,350,398	2/26/02	Breitenbach et al.	264	129	
/J.P./	6,284,800	9/4/01	Broder et al.	514	652	
/J.P./	6,264,917	7/24/01	Klaveness et al.	424	9.52	
/J.P./	6,228,864	5/8/01	Smith et al.	514	288	
/J.P./	6,221,368	4/24/01	Breitenbach et al.	424	400	
/J.P./	6,162,467	12/19/00	Miller et al.	424	468	
/J.P./	6,150,424	11/21/00	Breitenbach et al.	514	772.5	
/J.P./	6,120,802	9/19/00	Breitenbach et al.	424	464	
/J.P./	6,068,855	5/30/00	Leslie et al.	424	468	
/J.P./	6,051,253	04/18/00	Zettler et al.	424	465	
/J.P./	6,001,391	12/14/99	Zeidler et al.	424	467	
/J.P./	5,980,882	11/9/99	Eichman	424	78.12	
/J.P./	5,965,163	10/12/99	Miller et al.	424	468	
/J.P./	5,939,099	8/17/99	Grabowski et al.	424	488	
/J.P./	5,897,910	4/27/99	Rosenberg et al.	427	2.14	

## FOREIGN PATENT DOCUMENTS

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
/J.P./	EP 0 463 877	1/2/92	Europe	A61K	9/54	
/J.P./	WO 98/26767	6/25/98	WIPO	A61K	9/50	

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

/J.P./	Co-pending U.S. Application No. 10/225,543, filed August 22, 2002.
/J.P./	Co-pending U.S. Application No. 10/294,693, filed November 15, 2002.
/J.P./	Dorow et al., Effects of Single Oral Doses of Bisoprolol and Atenolol on Airway Function in Nonasthmatic Chronic Obstructive Lung Disease and Angina Pectoris, <i>Eur. J. Clin. Pharmacol.</i> , 31(2):143-7: 1986.

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001	Appn. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

## U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
/J.P./	Bailliart et al., Effects of Bisoprolol on Local Vascular Resistance, <i>Eur Heart J</i> , 8 Suppl M:87-93; 1987.					
/J.P./	Haffner et al., A Metabolic Assessment of The Beta, Selectivity of Bisoprolol, <i>J. Hum. Hypertens.</i> , 6(5):397-400, 1992.					
/J.P./	Horikiri et al., Pharmacokinetics and Metabolism of Bisoprolol Enantiomers in Humans, <i>J. Pharm. Sci.</i> , 87(3): 289-294, 1998.					
/J.P./	Janka et al., Influence of Bisoprolol on Blood Glucose, Glucosuria, and Haemoglobin A <sub>1</sub> in Noninsulin-Dependent Diabetics, <i>J. Cardiovasc. Pharmacol.</i> , 8 Suppl 11:S96-9; 1986.					
/J.P./	Kim, et al., Chiral Separation of $\beta$ -Blockers after Derivatization with (-)- $\alpha$ -Methoxy- $\alpha$ -(trifluoromethyl)phenylacetyl Chloride by Gas Chromatography, <i>Arch. Pharm. Res.</i> , 24(5):402-6, 2001.					
/J.P./	Kitaori, et al., CsF in Organic Synthesis. The First and Convenient Synthesis of Enantiopure Bisoprolol by Use of Glycidyl Nosylate, <i>Tetrahedron Lett.</i> , 39(20), 3173-3176, 1998.					
/J.P./	Klockow et al., Studies on The Receptor Profile of Bisoprolol, <i>Arzneimittelforschung</i> , 36(2):197-200, 1986.					
/J.P./	Nandel et al., Conformational Structure of Some $\beta_1$ -Blockers, Their Partitioning in Lipid and The Role of Parasubstituents, <i>Ind. J. Biochem. Biophys.</i> , 32(4); 207-212, 1995.					
/J.P./	Nandel et al., Modeling, Design, Chiral Aspects and Role of Para-Substituents in Aryloxypropranolamine Based $\beta$ -Blockers, <i>Ind. J. Biochem. Biophys.</i> , 36(1):29-35, 1999.					
/J.P./	Schliep et al., Antagonistic Effects of Bisoprolol on Several $\beta$ -Adrenoceptor-Mediated Actions in Anaesthetized Cats, <i>Eur. J. Pharmacol.</i> , 123(2):253-61, 1986.					
/J.P./	Schnabel et al., Binding Properties of $\beta$ -Blockers at Recombinant $\beta_1$ -, $\beta_2$ -, and $\beta_3$ -Adrenoceptors, <i>J. Cardiovasc. Pharmacol.</i> , 36(4):466-71, 2000.					
/J.P./	Wellstein et al., Reduction of Exercise Tachycardia in Man after Propranolol, Atenolol and Bisoprolol in Comparison to Beta-Adrenoceptor Occupancy, <i>Eur. Heart J.</i> , 8(Suppl. M):3-8, 1987.					

Examiner	/Jeffrey Palenik/	Date Considered	05/25/2007
----------	-------------------	-----------------	------------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001-00000	Appln. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

## U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
/J.P./	6,303,144 B1	10/16/01	Omura	424	457	
/J.P./	6,270,805 B1	8/7/01	Chen et al.	424	497	
/J.P./	6,214,385 B1	4/10/01	Heinicke et al.	424	497	
/J.P./	6,190,692 B1	2/20/01	Busetti et al.	424	451	
/J.P./	6,033,687	3/7/00	Heinicke et al.	424	497	
/J.P./	5,891,474	4/6/99	Busetti et al.	424	490	
/J.P./	5,834,024	11/10/98	Heinicke et al.	424	497	
/J.P./	5,834,023	11/10/98	Chen	424	497	
/J.P./	5,830,503	11/3/98	Chen	424	480	
/J.P./	5,788,987	8/4/98	Busetti et al.	424	480	

## FOREIGN PATENT DOCUMENTS

		Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
/J.P./		98/32425	July 30, 1998	PCT	A61K 9/28	9/00, 9/48	

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

/J.P./	J. K. Ghali et al., "Metoprolol CR/XL in Female Patients with Heart Failure: Analysis of The Experience In Metoprolol Extended-Release Randomized Intervention Trial in Heart Failure (MERIT-HF)," Circulation, April 2, 2002, Vol. 105, No. 13, pgs 1585-1591.
/J.P./	X. Deroubaix et al., "Comparative Bioavailability of a Metoprolol Controlled Release Formula and a Bisoprolol Normal Release Tablet after Single Oral Dose Administration in Healthy Volunteers," International Journal of Clinical Pharmacology and Therapeutics, February 1996, Vol. 34, No. 2, pgs. 61-70.
/J.P./	G.L. Plasker et al., "Controlled Release Metoprolol Formulations. A review of their Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Use In Hypertension and Ischaemic Heart Disease," Drugs, March 1992, Vol. 43, No. 3, pgs. 382-414.
/J.P./	S.P. Glasser et al., "Circadian Heart Rate Response to Chronotherapy Versus Conventional Therapy in Patients with Hypertension and Myocardial Ischemia," Clinical Cardiology, July 2000, Vol. 23, No. 7, pgs. 524-529.

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001-00000	Appln. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

/J.P./	A. C. Ross et al., "Chronopharmaceutical Drug Delivery From a Pulsatile Capsule Device Based on Programmable Erosion," Journal of Pharmacy and Pharmacology, Aug. 2000, Vol. 52, No. 8, pgs. 903-909.
/J.P./	M.H. Smolensky et al., "Medical Chronobiology: Concepts and Applications," American Review of Respiratory Disease, June 1993, Vol. 147, No. 6, pgs. S2-S19.
/J.P./	G.E. D'Alonzo et al., "Chronophysiological Determinants of Asthma," Annals New York Academy of Science, 1991, Vol. 618, pgs. 123-139.
/J.P./	M.H. Smolensky et al., "Chronopharmacology and Chronotherapy of Cardio-Vascular Medications: Relevance to Prevention and Treatment of Coronary Heart Disease," American Heart Journal, 1999, Vol. 137, No. 4, pgs. S14-S24.
/J.P./	M.C. Cohen et al., "Meta-Analysis of the Morning Excess of Acute Myocardial Infarction and Sudden Cardiac Death," American Journal of Cardiology, 1997, Vol. 79, pgs. 1512-1515.
/J.P./	W.J. Elliott, "Circadian Variation in the Timing of Stroke Onset: A Meta-Analysis," Stroke, May 1998, Vol. 29, No. 5, pgs. 992-996.
/J.P./	R. Manfredini et al., "Circadian Variation in Spontaneous Rupture of Abdominal Aorta," The Lancet, Feb. 1999, Vol. 353, pgs. 643-644.
/J.P./	M.T. Johstone et al., "The Pathophysiology of the Onset of Morning Cardiovascular Events," American Journal of Hypertension, April 1996, Vol. 9, No. 4, Part 3, pgs. 22S-28S.
/J.P./	M.W. Millar-Craig et al., "Circadian Variation of Blood-Pressure," The Lancet, April 1978, Vol. 1, No. 8068, pgs. 795-797.
/J.P./	J.A. Staessen et al., "Nocturnal Blood Pressure Fall on Ambulatory Monitoring in a Large International Database," Hypertension, January 1997, Vol. 29, No. 1, Part 1, pgs. 30-39.
/J.P./	W. J. Elliott, "Circadian Variation in Blood Pressure Implications for the Elderly Patient," American Journal of Hypertension, February 1999, Vol. 12, No. 2, Part 2, pgs. 43S-49S.
/J.P./	H. Sternberg, "Altered Circadian Rhythm of Blood Pressure in Shift Workers," Journal of Human Hypertension, May 1995, Vol 9, No. 5, pgs. 349-353.
/J.P./	I. Kawachi et al., "Prospective Study of Shift Work and Risk of Coronary Heart Disease in Women," Circulation, December 1, 1995, Vol. 92, No. 11, pgs. 3178-3182.
/J.P./	H. Boggild et al., "Shift Work, Risk Factors and Cardiovascular Disease," Scandinavian Journal of Work, Environment & Health, April 1999, Vol. 25, No. 2, pgs. 85-99.
/J.P./	A. F. Khouri et al., "The Early Morning Rise in Blood Pressure Is Related Mainly to Ambulation," American Journal of Hypertension, June 1992, Vol. 5, No. 6, Part 1, pgs. 339-344,
/J.P./	W. J. Elliott et al., "Drug Delivery Systems For Antihypertensive Agents," Blood Pressure Monitoring, 1997, Vol. 2, No. 1, pgs. 53-60.
/J.P./	S. K. Gupta et al., "The Effect of Food, Time of Dosing, and Body Position on the Pharmacokinetics and Pharmacodynamics of Verapamil and Norverapamil," The Journal of Clinical Pharmacology, 1995, Vol. 35, No. 11, pgs. 1083-1093.

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001-00000	Appn. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

/J.P./	W.B. White et al., "Nocturnal Dosing of a Novel Delivery System of Verapamil for Systemic Hypertension," The American Journal of Cardiology, August 1995, Vol. 76, pgs. 375-380.
/J.P./	K. Kario et al., "Nocturnal Fall of Blood Pressure and Silent Cerebrovascular Damage in Elderly Hypertensive Patients," Hypertension, January 1996, Vol. 27, No. 1, pgs. 130-135.
/J.P./	S. S. Hayreh et al., "Nocturnal Arterial Hypotension and Its Role in Optic Nerve Head and Ocular Ischemic Disorders," American Journal of Ophthalmology, May 1994, Vol. 117, pgs. 603-624.
/J.P./	W.B. White et al., "Comparison of Effects of Controlled Onset Extended Release Verapamil at Bedtime and Nifedipine Gastrointesinal Therapeutic System on Arising on Early Morning Blood Pressure, Heart Rate, and the Heart Rate-Blood Pressure Product," The American Journal of Cardiology, February 1998, Vol. 81, pgs.424-431.
/J.P./	R.B. Anderson et al., "Physical Symptoms Distress Index," Archives of Internal Medicine, April 1999, Vol. 159, pgs. 693-700.
/J.P./	W. H. Frishman et al., "Comparison of Controlled-Onset, Extended-Release Verapamil With Amlodipine and Amlodipine Plus Atenolol on Exercise Performance and Abulatory Ischemia in Patients With Chronic Stable Angina Pectoris," The American Journal of Cardiology, February 1999, Vol. 83, pgs 507-514.
/J.P./	H.R. Black et al., "Rationale and Design for the Controlled ONset Verapamil INvestigation of Cardiovascular Endpoints (CONVINCE) Trial," Controlled Clinical Trials, August 1998, Vol. 19, No. 4, pgs. 371-387.
/J.P./	H.R. Black et al., "Baseline Characteristics and Early Blood Pressure Control in the CONVINCE Trial," Hypertension, January 2001, Vol. 37, No. 1, pgs. 12-18.

Examiner	/Jeffrey Palenik/	Date Considered	06/21/2007
----------	-------------------	-----------------	------------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609, draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**Notice of References Cited**

Application/Control No.

09/488,103

Applicant(s)/Patent Under

Reexamination

STARK ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US-5137733 /J.P./	08-1992	Noda et al.	424	497
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification	
*	N	WO 98/32426 /J.P./	07-1998	WIPO	Busetti et al.	A61K	9/36
	O						
	P						
	Q						
	R						
	S						
	T						

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<b>Notice of References Cited</b>		Application/Control No.	Applicant(s)/Patent Under Reexamination STARK ET AL	
		09/488,103	Examiner	Art Unit 1615
Robert M. Joynes		Page of		

**U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
A	US-			
B	US-			
C	US-			
D	US-			
E	US-			
F	US-			
G	US-			
H	US-			
I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

**FOREIGN PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N					
O					
P					
Q					
R					
S					
T					

**NON-PATENT DOCUMENTS**

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)	
U	Handbook for Pharmaceutical Excipients, Second Edition, Polymethacrylates, pp. 362-66, 1994.	/J.P./
V		
W		
X		

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.